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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,634	11/12/2003	Gary T. Neel	02-1134-d	7985

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,634	NEEL ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25-32* is/are allowed.

6)☒ Claim(s) *33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,728,074 to Castellano in view of US Patent No. 5,837,546 to Allen et al. and US Patent No. 6,591,125 to Buse et al.

Castellano teaches a method of using a test strip to test a blood sample comprising, wherein the user inserts the test strip 204 into a meter 202, the meter 202 being in sleep mode (col. 14, lines 37-40; col. 20, line 65-col. 21, line 5) and responsively entering an active mode. A blood sample is applied the sample chamber of the test strip 204 (col. 14, lines 52-56). The meter 202 detects the blood sample in the chamber (col 14, lines 56-57; col. 15, lines 9-12) and makes a measurement of blood glucose based on a current measurement (col. 14, lines 47-49). Castellano is silent as to the details of the meter entering the active mode from the sleep mode and detecting the blood sample in the chamber and the current measurement.

Allen discloses an test strip having an auto on conductor formed by two sets of electrodes 22, 36 and the meter detects an auto-on current through the conductor 22, 36 and responsively enters an active mode from sleep mode (figs. 2, 3, 8; col. 8, line 54-col. 9, line 4; col. 14, line 53-col. 15, line 12; col. 15, lines 28-41 of Allen). Therefore it would have been obvious to one of ordinary skill in the art to use the means described

by Allen of activating the meter by insertion of a test strip in the invention of Castellano, since Castellano teaches an analyte meter capable of entering an active mode from a sleep mode upon insertion of a test strip and Allen describes an appropriate mean for doing so. The combination of Castellano in view of Allen is silent as to the details of the meter detecting the sample in the sample chamber and the current measurement.

Buse teaches a test strip having a working electrode 502, 522 and counter electrodes 510,512 or 530, 532, 534 (figs. 18A-C, 19A-C; col. 31, lines 44-57; col. 34, lines 1-9). During operation, the meter applies a voltage between fill electrodes 502, 510 and measures a fill-detect current flowing between the fill-detect electrode 502,522 (col. 51, lines 38-50). Once the meter has determined that the sample chamber has been filled, the meter begins reading the analyte concentration in the sample by applying an assay voltage between the working electrode 502 and a counter electrode 510 (col. 52, lines 53-63) and measures a resulting current to derive an analyte concentration (col. 38, lines 29-35; col. 38, line 54-col. 9, line 33; col. 39, lines 59-67 of Buse). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the means described by Buse for detecting the blood sample in the chamber and for detecting a current measurement as that of Castellano, as modified by Allen, since Castellano, as modified, teaches a meter capable of detecting the presence of a sample in a sample chamber of a test strip and capable of determining an glucose concentration based on a current measurement, and Buse describes a means for doing so.

Castellano, as modified by Allen and Buse teaches a test strip having a working electrode and two counter electrodes, wherein a working electrode and one of the counter electrodes are used as the pair of fill-detect electrode, rather than providing a separate pair of fill-detect electrodes. However, the applicants have not disclosed that providing the fill-detect electrodes separately from the working and counter electrodes solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with the test strip having a shared electrode used both for detecting a blood sample and for measuring a current indicative of a test result. Accordingly, the use of separate electrodes is deemed to be a design consideration which fails to patentably distinguish over the prior art of Castellano, as modified by Allen and Buse.

Regarding claim 34, the auto-on current develops an auto-on voltage drop across the auto-on conductor, and the meter measures this auto-on voltage drop (col. 15, lines 9-42 of Allen)

Regarding claim 35, if the fill-detect current reaches a fill-detect threshold value within a predetermined time period, the meter provides a user-discernibly indication (col. 15, lines 9-12 of Castellano; col. 51, lines 38-50, col. 52, lines 53-56 of Buse et al.)

Regarding claim 36, the meter may further detect the blood sample in the sample chamber by applying a drop-detect voltage between the working and counter electrodes and measuring a drop-detect current between the electrodes (figs. 19A-c, 20A-C; col. 52, lines 9-16 of Buse et al.)

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano in view of Allen et al. and Buse et al., as applied to claims 33-36 above. Castellano, as modified, fails to teach the meter starting an incubation time period. However, Buse teaches that the sample may be incubated for a period of time (col. 52, line 65-col. 53, line 16 of Buse et al.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to incubate the sample for a time period in order to increase the rate of diffusion, oxidation or reduction of an analyte (col. 52, lines 66-67 of Buse et al.)

Allowable Subject Matter

Claims 25-34 are allowed. The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 25-34, the prior art of record fails to teach or fairly suggest a method of measuring glucose in a blood sample wherein a meter validates the fill-detect electrodes on a test strip by applying a second validation voltage between the fill-detect electrodes while a first validation voltage is applied between the working and counter electrodes on the test strip in order to validate the working and counter electrodes. US Patent No. 5,438271 to White et al. teaches a method of measuring glucose in a blood sample wherein the meter validates the working 14 and counter 12 electrodes by applying a first validation voltage between the working and counter electrodes (col. 3, lines 39-54 and lines 60-67; col. 4, lines 24-35; fig. 3 of White). However, the reference fails to teach applying a second validation voltage between fill-

detect electrodes while the first validation voltage is applied between the working and counter electrodes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US Patent No. 6,733,655 to Davies et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER